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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/673,221

10/06/2000

Mark Rupert Tucker

HA01-P01

3673

881

7590

10/20/2003

LARSON & TAYLOR, PLC  
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SUITE 900  
ALEXANDRIA, VA 22314

EXAMINER

NASH, BRIAN D

ART UNIT

PAPER NUMBER

3721

DATE MAILED: 10/20/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/673,221

Applicant(s)

TUCKER, MARK RUPERT

Examiner

Brian D Nash

Art Unit

3721

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This action is in response to applicant's amendment received 17 September 2003.

Examiner acknowledges cancellation of all previously pending claims 20-39 and the addition of new claims 40-56. The pending claims are now 40-56.

#### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 40-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,769,974 to Davis in view of US 5,656,285 to Sablotsky et al. Davis discloses the invention substantially as claimed including a process having first and second (16,18) feeding strips (see Davis, Fig. 1), heat-sealing the strips together both longitudinally (26,28) and transversely (32,34), introducing a liquid via a tube (30) into a pouch (40); a transverse cutting step (see Davis, column 6, lines 53-55); creating two laterally adjacent pouches (see Davis, column 5, lines 62-63); flushing the pouches with a gas (see Davis, column 12, lines 48-61) via a tube (82,84,86); filling the pouches at a low pressure (see Davis, column 12, lines 15-25); and adjusting number or size of the pouches made (see Davis, column 7, lines 48-53). Davis does not disclose a first, multi-layered strip or a cutting cylinder for lateral separation of the pouches.

However, Sablotsky teaches the use of a multi-layered strip having a backing layer, an adhesive layer, and a release liner to form transdermal patches (see Sablotsky, column 3, lines 41-44) and a cutting cylinder (18,22) for the purpose of making transdermal patches in a singular and continuous mechanical motion.

Regarding claim 40 and the use of a multi-layered strip, it would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the multi-layered strip, as taught by Sablotsky, with the process of Davis. The manufacture of transdermal patches is well known in the art and although the process and apparatus shown by Davis serves a different functional purpose, its operation and method are analogous to applicant's claimed invention.

Furthermore, the amendments to the independent claim wherein "an accurate predetermined dosage" is introduced into the pouch and wherein the introduction of the liquid or gel into the pouch is "in synchronous with the linear speed at which the strips are fed" are acknowledged; however, please note that the apparatus and process of Davis inherently introduces a predetermined dosage into the pouches. It is also inherent to the apparatus and process of Davis that the filling of the pouches via the filling tube (30) is synchronous with the linear speed at which the strips (16,18) are fed.

### ***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Nash whose telephone number is (703) 305-4959. The examiner can normally be reached on Monday – Thursday from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached at 703 308-2187.

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The fax number for this Group is: 703-872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Brian D. Nash  
15 October 2003

A handwritten signature in black ink, appearing to read 'Rinaldi I. Rada', with a stylized, flowing script.

Rinaldi I. Rada  
Supervisory Patent Examiner  
Group 3700